REMARKS

In the Office Action dated September 23, 2002, the drawings were objected to under 37 C.F.R. §1.84(p)(5), and the disclosure was objected to, because Figure 3 included reference numeral 112, but this reference numeral was not used in the written portion of the specification. The specification has been amended to insert this reference numeral at the appropriate location, and since this reference numeral was already used in Figure 3 as originally filed, and since the amended description clearly pertains to that portion of Figure 3, no new matter is added thereby.

Claims 1-8 were rejected under 35 U.S.C. §102(b) as being anticipated by Winn et al. This rejection is respectfully traversed for the following reasons.

Applicants respectfully submit the Winn et al. reference discloses a conventional high-frequency oscillator ventilator of the type described in the introductory portion of the present application, wherein oscillations are produced in a column of gas, that is in communication with the airways of a patient, by a piston-type oscillator. This type of oscillator is described, for example, in the paragraph bridging pages 2 and 3 of the present specification, and the disadvantages associated with this known type of HFO ventilator are discussed at page 3.

This disadvantages are overcome in the HFO ventilator disclosed and claimed in the present application by the arrangement for alternately introducing a volume of *additional* gas into a gas conduit in connection with a patient's airways, and withdrawing this volume of additional gas from the conduit, to produce pressure oscillations. Applicants submit it should be clear from the language of original claim 1 that the "additional gas" is intended to mean gas that is in addition to the bias gas,

however, claim 1 has been editorially amended to make this explicit in the language of claim 1.

In general, it is the position of the present Applicants that the Winn et al. reference does not disclose the use of such additional gas, in addition to the bias gas, and in fact it would not even be possible to introduce gas in addition to the bias gas into the relevant portion of the Winn et al. reference.

In the ventilator disclosed in Winn et al. as shown in Figure 1, a line proceeds between the airways 12 and the oscillator 14 and has an opening adapted for gas connection to the airways 12 of a patient. Since this line is connected to the patient's airways, it corresponds to the "first gas conduit" of claim 1 of the present application. This line in Winn et al. has a bias gas flow inlet at the end of line 24, and a bias gas flow outlet formed by the line 36 that is connected to the exhalation valve 34. This inlet and outlet define a flow path for bias gas from the blender 18 within the aforementioned first conduit. This is described at column 3, lines 25-63 in Winn et al.

The Winn et al. reference further more employs a high-frequency oscillator 14 driven by a piston 16, as described at column 3, lines 26-36. This oscillator 14 is connected at an end of the aforementioned first conduit that is opposite the opening for connection to the patient's airways. Winn et al. explicitly state that the oscillator 14 operates to move a column of gas within the airways 12 back and forth, at column 7, lines 61-63. This is completely consistent with aforementioned description in the introduction of the present application regarding conventional HFO ventilators.

The only source of gas within the Winn et al. system is from the blender 18, and this is used to establish air flow equilibrium within the first conduit, so that the

bias flow is created, by virtue of air bleeding from the exhalation valve 34 at the same rate as air enters from the line 24 connected to the blender 18. This establishment of the bias gas flow is described in Winn et al. at column 8, lines 19-29.

Moreover, the oscillator 14 is connected only after this equilibrium flow is established *and fixed* as described at column 8, lines 41-42 of Winn et al. The oscillator 14 operates to withdraw gas from the first conduit and to return gas to the first conduit, thereby producing the aforementioned pressure oscillations around a mean (average) airway pressure that is established by the aforementioned fixed bias flow. This is explained at column 4, lines 48-59 in Winn et al.

It is clear from Figure 1 in Winn et al. that the oscillator 14 is in direct fluid communication with the patient's airways 12 via the first conduit (also as stated at column 3, lines 33-55 in Winn et al.), and is connected to no other supply of gas. Therefore, there is no structure for introducing any additional gas into the system by the operation of the oscillator 14 in the ventilator disclosed in Winn et al., nor is there even an opportunity for the introduction of such an additional gas in Winn et al.

Therefore, the oscillator 14 disclosed in the Winn et al. reference does not operate as set forth in claim 1 of the present application. Specifically, the operator disclosed in the Winn et al. reference does not operate to introduce and withdraw an amount of gas in addition to that which is already supplied by the bias flow in order to establish the mean airway pressure. Instead, the operator 14 disclosed in Winn et al. operates to alternately compress and expand the gas that is already present in the first conduit.

The Winn et al. reference therefore does not disclose all of the elements of independent claim 1 as arranged and operating in that claim and thus does not anticipate claim 1 under 35 U.S.C. §102(b). Dependent claims 2-8 add further structure to the novel combination of independent claim 1, and therefore are not anticipated by Winn et al. for the same reasons discussed above in connection with claim 1.

Claim 9 was rejected under 35 U.S.C. §103(a) as being unpatentable over Winn et al.

Claim 9 depends from claim 1 as well, and therefore the above distinctions between claim 1 and the teachings of Winn et al. are relevant to the obviousness rejection of claim 9. Since there is no suggestion whatsoever in the Winn et al. reference to introduce a volume of additional gas, in addition to the bias gas, for the purpose of producing high-frequency oscillations, nor is there even any structure in the Winn et al. reference which would allow the introduction of such an additional gas, it would not have been obvious to a person of ordinary skill in the art to modify the Winn et al. structure to arrive at the subject matter of claim 9, which embodies the subject matter of claim 1 therein. Claim 9, therefore, would not have been obvious to a person of ordinary skill in the art based on the teachings of Winn et al. under the provisions of 35 U.S.C. §103(a).

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

Claim 2 has been presented herein in "clean" form, embodying the handwritten material provided by the inventors in the original application. Since this material is initialed and dated by the inventors, it is a part of the original content of

claim 2, and does not constitute an "amendment" to claim 2. Therefore, since no "change" has been made in claim 2, it is not necessary to include claim 2 in the attachment showing marked-up versions of portions of the application which have been amended.

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

Please amend the paragraph beginning at page 10, line 8 as follows:

In Fig. 3 an HFO ventilator 86 is shown having a primary gas conduit 88 with a patient opening 90 at one end and with an opening 92 at the opposite end connected to an extraction device 94. The extraction device 94 has a variable gas holding volume 96 which has a reciprocally moveable element, again shown as a piston 98, as a defining wall section. The piston 98 connects to a drive unit 100 which reciprocates the piston 98 at an operating frequency of the HFO ventilator 86 dependent on an oscillating control signal provided by the control signal generator 102. A bias gas flow inlet 104 connects to the inside of the primary conduit 88 at a location proximal the patient opening 90 and a gas outlet 106 connects to the inside of the primary conduit 88 via a humidifier 122b at a location distal the patient opening 90 and in gas communication with the variable gas holding volume 96. The inlet 104 and outlet 106 are disposed to define a flow path therebetween for bias gas within the primary conduit 88. A one-way valve 108, for example a mushroom valve, is located at the gas outlet 106 and arranged to allow the only the venting of gas from the primary conduit 88. This valve 108 is adapted to open only when pressure within the primary conduit 88 reaches a predetermined and possibly adjustable level. In this way a desired average airway pressure can be established by the HFO ventilator 86. A further one-way valve 110 is located within the primary conduit 88 to prevent gas passing from the variable volume 96 and through the patient opening 90 as the piston 98 is moved to reduce the volume of the variable volume 96. A secondary conduit 112 is provided with an opening 114 in the primary conduit 88 through which

gas may be directed to intersect the bias flow path and move towards the patient opening 90. A gas pulse generator 116 has a controllable on/off valve 118 which is switched under the control of the control signal generator 102 to alternately allow and prevent passage of gas from a [pressurized] pressurized source of an additional gas (not shown) which connects to an inlet 120 of the gas pulse generator 116. Also provided within the gas pulse generator 116, in-line between the inlet 120 and the valve 118, is a humidifier 122 which conditions the additional gas before it is supplied to the primary conduit 88.

IN THE CLAIMS

Please amend claim 1 as follows:

1. (Amended) A high-frequency oscillator (HFO) ventilator comprising;

a first gas conduit having an opening adapted for gas connection with a patient's airways and a bias gas flow inlet and a bias flow outlet disposed to define therebetween a flow path for a bias gas within the first conduit;

an oscillator for inducing pressure oscillations in gas within the first conduit to move said gas along a path intersecting the flow path for a bias gas alternately into and out of the opening at a predetermined high-frequency, said oscillator comprising an arrangement, for alternately introducing a volume of additional gas, in addition to said bias gas into and withdrawing at least the volume of gas from the first gas conduit to induce the pressure oscillations.